

1653

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT

(Under 37 CFR 1.97(b) or 1.97(c))

Docket No. **#5**
14750

In Re Application Of: **Ronald Buelow, et al.**

MAR 29 2002

Serial No.
09/921,819

Filing Date
August 3, 2001

Examiner
Unassigned

Group Art Unit
1653

Title: **PRODUCTION OF HUMANIZED ANTIBODIES IN TRANSGENIC ANIMALS**

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Address to:
Assistant Commissioner for Patents
Washington, D.C. 20231

37 CFR 1.97(b)

1. ☒ The Information Disclosure Statement submitted herewith is being filed within three months of the filing of a national application; within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; or before the mailing date of a first Office Action on the merits, whichever event occurs last.

37 CFR 1.97(c)

2. ☐ The Information Disclosure Statement submitted herewith is being filed after three months of the filing of a national application, or the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; or after the mailing date of a first Office Action on the merits, whichever occurred last but before the mailing date of either:

1. a Final Action under 37 CFR 1.113, or
 2. a Notice of Allowance under 37 CFR 1.311,
- whichever occurs first.

Also submitted herewith is:

- ☐ a certification as specified in 37 CFR 1.97(e);

OR

- ☐ the fee set forth in 37 CFR 1.17(p) for submission of an Information Disclosure Statement under 37 CFR 1.97(c).

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(Only complete if Applicant elects to pay the fee set forth in 37 CFR 1.17(p))

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I certify that this document and fee is being deposited on March 25, 2002 with the U.S. Postal Service as first class mail under 37 C.F.R. 1.8 and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Signature of Person Mailing Correspondence

Michelle Mustafa

Typed or Printed Name of Person Mailing Correspondence

Dated: March 25, 2002

Edward W. Grolz, Reg. No. 33,705
SCULLY, SCOTT, MURPHY & PRESSER
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Garden City, NY 11530
(516) 742-4343

EWG:ahs

CC:

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENTS

Applicant(s): Ronald Buelow, et al.

Examiner: Unassigned

Serial No: 09/921,819

Art Unit: 1653

Filed: August 3, 2001

Docket: 1475

For: PRODUCTION OF HUMANIZED
ANTIBODIES IN TRANSGENIC ANIMALS

Dated: March 25, 2002

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Assistant Commissioner for Patents
United States Patent and Trademark Office
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Sir:

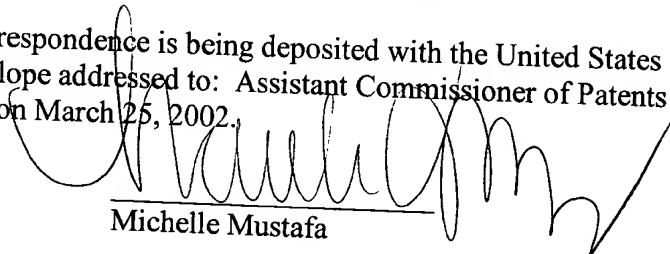
In accordance with 37 C.F.R. §§ 1.97 and 1.98, it is requested that the following references, which are also listed on the attached Form PTO-1449, be made of record in the above-identified case.

1. United States Patent No. 5,814,318, dated September 29, 1998, issued to Lonberg, et al.;
2. United States Patent No. 5,545,807, dated August 13 1996, issued to Surani, et al.;
3. United States Patent No. 5,570,429, dated October 29, 1996, issued to Paddock;

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner of Patents and Trademarks, Washington, D.C. 20231 on March 25, 2002.

Dated: March 25, 2002


Michelle Mustafa

4. United States Patent No. 5,416,260, dated May 16, 1995, issued to Koller et al.;
5. United States Patent No. 5,567,607, dated October 22, 1996, issued to Zhao, et al.;
6. United States Patent No. 5,453,357, dated September 26, 1995, issued to Hogan;
7. United States Patent No. 5,639,457, dated June 17, 1997, issued to Brem, et al.;
8. United States Patent No. 5,874,299, dated February 23, 1999, issued to Lonberg, et al.;
9. European Patent No. EP 0 438 474 B1, dated May 15, 1996, issued to Bruggemann, et al.;
10. International Publication No. WO 00/75300 A2, dated December 14, 2000, issued to Paul Ditullio, et al.;
11. Knight, et al., "Organization and Polymorphism of Rabbit Immunoglobulin Heavy Chain Genes", J. Immunol., pp. 1245-1250 (1985);
12. Huang and Stollar, "A Majority of Ig H Chain cDNA of Normal Human Adult Blood Lymphocytes Resembles cDNA for Fetal Ig and Natural Autoantibodies", The American Association of Immunology, Vol. 151, pp. 5290-5300 (1993);
13. Knight & Becker, "Molecular Basis of the Allelic Inheritance of Rabbit Immunology VH Allotypes: Implications for the Generation of Antibody Diversity", Cell, Vol. 60, pp. 963-970 (1990);
14. Pritsch, et al., "V Gene Usage by Seven Hybrids Derived From CD5⁺ B-Cell Chronic Lymphocytic Leukemia and Displaying Autoantibody Activity", Blood, Vol. 82, No. 10, pp. 3103-3112 (1993);
15. Lautner-Rieske, et al., "The Human Immunoglobulin χ Locus. Characterization of the Duplicated A Regions*", Eur. J. Immunol., Vol. 22, No. 4, pp. 1023-1029 (1992);
16. Lieberman, et al., "Structure of a Germline Rabbit Immunoglobulin V χ -Region Gene: Implications for Rabbit V χ -J χ Recombination", The Journal of Immunology, Vol. 133, No. 5, pp. 2753-2756 (1984);

17. Fan, et al., "Transgenic Rabbit Models for Biomedical Research: Current Status, Basic Methods and Future Perspectives", Pathology International, Vol. 49, No. 7, pp. 583-594 (1999);
18. Zhang, et al., "DNA Cloning By Homologous Recombination in Escherichia Coli", Nature Biotechnology, Vol. 18, No. 12, pp. 1314-1317 (2000);
19. Kametani, et al., "Comparative Studies on the Structure of the Light Chains of Human Immunoglobulins", J. Biochem., Vol. 93, No. 2, pp. 421-429 (1983);
20. McCormack, et al. "Chicken IgL Rearrangement Involves Deletion of a Circular Episome and Addition of Single Nonrandom Nucleotides to Both Coding Segments", Cell, Vol. 56, pp. 785-791 (1989);
21. Matthyssens and Rabbitts, "Structure and Arrangement of Human Heavy Chain Variable Region Genes", The Immune System, Vol. 1, pp. 132-138 (1981);
22. Etches, et al., "Strategies for the Production of Transgenic Chickens", Methods in Molecular Biology, Vol. 62, pp. 433-450;
23. Pain, et al., "Chicken Embryonic Stem Cells and Transgenic Strategies", Cells Tissues, Organs, Vol. 165, Nos. 3-4, pp. 212-219 (1999);
24. Sang, H., "Transgenic Chickens - Methods and Potential Applications", TIBTECH, Vol. 12, pp. 415-420 (1994);
25. Brem, et al., "YAC Transgenesis in Farm Animals: Rescue of Albinism in Rabbits", Molecular Reproduction & Development, Vol. 44, pp. 56-62 (1996);
26. Stice, et al., "Nuclear Reprogramming in Nuclear Transplant Rabbit Embryos", Biology of Reproduction, Vol. 39, pp. 657-664 (1988);
27. McCartney-Francis, et al., "Expression of K2 Isotype mRNA in Normal and Basilea Rabbits", Molecular Immunology, Vol. 24, No. 4, pp. 357-364 (1987);
28. Allegrucci, et al., "Preferential Rearrangement in Normal Rabbits of the 3' V_Ha Allotype Gene that is Deleted in Alicia Mutants...", Eur. J. Immunol., Vol. 21, pp. 411-417 (1991);
29. Frommel, et al, "Metabolism of γ G and γ M Immunoglobulins in Normal and Hypogammaglobulinemic Chickens", The Journal of Immunology, Vol. 105, No. 1, pp. 1-6 (1970);
30. Benedict, et al, "Inherited Immunodeficiency in Chickens: A Model for Common Variable Hypogammaglobulinemia in Man", Adv. Exp. Med. Biol., Vol. 88, No. 2, pp. 197-205 (1977);

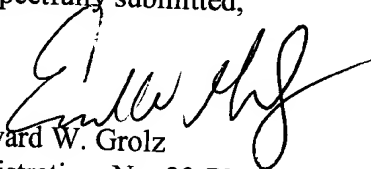
31. T. Wakayama, et al., "Full-Term Development of Mice from Enucleated Oocytes Injected with Cumulus Cell Nuclei", Nature, Vol. 394, pp. 369-374 (1998);
32. Cibelli, et al., "Transgenic Bovine Chimeric Offspring Produced from Somatic Cell-Derived Stem-Like Cells", Nature BioTechnology, Vol. 16, pp. 642-646 (1998);
33. Ishida, et al., "Production of a Diverse Repertoire of Human Antibodies in Genetically Engineered Mice", Microbiol. Immunol., Vol. 42, No. 3, pp. 143-150 (1998);
34. Tomizuka, et al., "Double Trans-Chromosomic Mice: Maintenance of Two Individual Human Chromosome Fragments Containing Ig Heavy and κ loci and Expression of Fully Human Antibodies", National Academy of Sciences, Vol. 97, Issue 2, pp. 722-727 (2000);
35. Sale, et al., "Ablation of XRCC2/3 Transforms Immunoglobulin V Gene Conversion into Somatic Hypermutation", Nature, Vol. 412 (2001);
36. Lanza, et al., "Extension of Cell Life-Span and Telomere Length in Animals Cloned from Senescent Somatic Cells", Science, Vol. 288, pp. 665-669 (2000);
37. Polejaeva, et al., "Cloned Pigs Produced by Nuclear Transfer from Adult Somatic Cells", Nature, Vol. 407, (2000);
38. K.J. McCreath, et al., "Production of Gene-Targeted Sheep by Nuclear Transfer from Cultured Somatic Cells", Nature, Vol. 405 (2000);
39. D. Bucchini, et al., "Rearrangement of a Chicken Immunoglobulin Gene Occurs in the Lymphoid Lineage of Transgenic Mice", Nature, Vol. 326, pp. 409-411 (1987);
40. Knight, et al., "Generating the Antibody Repertoire in Rabbit", Advances in Immunology, Vol. 56, pp. 179-218 (1994);
41. Langman, et al., "A Theory of the Ontogeny of the Chicken Humoral Immune System: The Consequences of Diversification by Gene Hyperconversion and its Extension to Rabbit", Res. Immunology, Vol. 144, pp. 422-446 (1993);
42. Campbell, et al., "Sheep Cloned by Nuclear Transfer from a Cultured Cell Line", Nature, Vol. 380, pp. 64-66 (1996);
43. Stice, et al., "Cloning: New Breakthroughs Leading to Commercial Opportunities", Theriogenology, Vol. 49, pp. 129-138 (1998);

44. Cibelli, et al., "Cloned Transgenic Calves Produced from Nonquiescent Fetal Fibroblasts", Science, Vol. 280, pp. 1256-1258 (1998);
45. Schnieke, et al., "Human Factor IX Transgenic Sheep Produced by Transfer of Nuclei from Transfected Fetal Fibroblasts", Science, Vol. 278, pp. 2130-2133 (1997).

Applicants are submitting copies of the above-cited references.

Inasmuch as this Information Disclosure Statement is being submitted in accordance with the schedule set out in 37 C.F.R. § 1.97(b), no statement or fee is required.

Respectfully submitted,



Edward W. Grolz
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Form PTO-1449 U.S. DEPARTMENT OF COMMERCE
(REV. 7-80) PATENT AND TRADEMARK OFFICE

Atty. Docket No.: 14750

Serial No.: 09/921,819

LIST OF PRIOR ART
CITED BY APPLICANT
(Use several sheets if necessary)

Applicants: Ronald Buelow, et al.

Filing Date: August 3, 2001

Group: 1653

U.S. PATENT DOCUMENTS

EXAMINER INITIAL*		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE (if appropriate)
	AA	5,814,318	9/29/98	Lonberg, et al.			
	AB	5,545,807	8/13/96	Surani, et al.			
	AC	5,570,429	10/29/96	Paddock			
	AD	5,416,260	5/16/95	Koller et al.			
	AE	5,567,607	10/22/96	Zhao, et al.			
	AF	5,453,357	9/26/95	Hogan			
	AG	5,639,457	6/17/97	Brem, et al.			
	AH	5,874,299	2/23/99	Lonberg, et al.			

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	AI	EP 0438474B1	5/15/96	Europe				
	AJ	WO 00/75300A2	12/14/00	PCT				

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	AK	Knight, et al., "Organization and Polymorphism of Rabbit Immunoglobulin Heavy Chain Genes", <u>J. Immunol.</u> , pp. 1245-1250 (1985)
	AL	Huang and Stollar, "A Majority of Ig H Chain Cdna of Normal Human Adult Blood Lymphocytes Resembles CDNA for Fetal Ig and Natural Autoantibodies", <u>The American Assoc. of Immunology</u> , Vol. 151, pp. 5290-5300 (1993)
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